

Message Text

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ORIGIN HEW-06

INFO OCT-01 EUR-12 ISO-00 OES-05 EB-07 AGR-10 /041 R

66619

DRAFTED BY:DHEW/FDA:JRWEINROTH

APPROVED BY:OES/APT/BMP:MBEAUBIEN

DHEW/OIH:MACODDING

EUR/CE:BAFALTIN(INFO)

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P 292105Z OCT 75

FM SECSTATE WASHDC

TO AMEMBASSY BERN PRIORITY

UNCLAS STATE 256427

E.O. 11652: N/A

TAGS: OGEN, ETRD, TBIO, SZ

SUBJECT: PYROGEN AND PARTICULATE CONTAMINATION OF BUFFERED
DILUENTS

1. FDA ADVISES THAT THE:

PRODUCTS:

A. BUFFERED DILUENT, STERILE MULTIPLE DOSE VIALS, CONTAINING
DOSIUM CHLORIDE, POTASSIUM PHOSPHATE, SODIUM PHOSPHATE, PHENOL,
WATER-PACKAGED IN 2.7 CC., 4 CC., 4.5 CC., 5 CC., 9 CC., 10 CC.,
18 CC., 27 CC., 45 CC., 100 CC., AND 125 CC., MULTIPLE DOSE
GLASS VIALS. ALL SIZES ARE PACKED UNDER THE PUREX LABEL.

B. COCA'S SOLUTION, STERILE MULTIPLE DOSE VIALS, CONTAINING
SODIUM CHLORIDE, SODIUM BICARBONATE, PHENOL, WATER-PACKED IN
9 CC. MULTIPLE DOSE GLASS VIALS UNDER THE PUREX LABEL.

LOT NUMBERS: S0106D S0112D T0403D

S0108D T0102D T0104D

S0109D T0103D T0105D

S0110D T0203D T0205D

(COCA'S SOLUTION)

S0111D T0303D T0206D

S0311D T0306D

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ARE BEING RECALLED FROM THE MARKET.

MANUFACTURER:

PUREX LABORATORIES, INC.

DIVISION OF CLINICAL SCIENCES INC.

WEST STREET

EAST HANOVER, NEW JERSEY 07936

REASON FOR ADVISORY: INSPECTION OF THE FIRM ON JUNE 13-20, 1975
REVEALED NUMEROUS CRITICAL DEVIATIONS FROM CURRENT GOOD MANUFACTURING PRACTICE REGULATIONS. SAMPLES COLLECTED WERE FOUND TO BE PYROGENIC AND IN ADDITION, CONTAINED PARTICULATE MATTER.
THE FIRM MAILED A LETTER TO ALL CONSIGNEES ON SEPTEMBER 30, 1975 WHICH RECALLS ALL LOTS MANUFACTURED BETWEEN AUGUST 1, 1974 AND JUNE 30, 1975. THE LETTER STATES IN PART "IT IS FELT THAT ALL LOTS OF BUFFERED DILUENT MANUFACTURED PRIOR TO JUNE 1975 LEAVE OPEN SERIOUS QUESTIONS CONCERNING SAFETY. IN ORDER TO INSURE THAT LOTS OF BUFFERED DILUENT CAN BE UTILIZED WITH MAXIMUM CONFIDENCE, WE ASK YOU TO IMMEDIATELY RETURN LOT NUMBER---SHIPPED TO YOU ON ---. PLEASE UTILIZE THE ENCLOSED LABELING ON THE OUTSIDE OF YOUR PACKAGE TO INSURE PROPER QUARANTINE OF THE RETURNED MATERIAL AND PROMPT REPLACEMENT."

2. POST IS REQUESTED TO CONTACT FOREIGN CONSIGNEE TO DETERMINE IF HE IS FAMILIAR WITH RECALL AND DISPOSITION OF PRODUCT.

3. FOREIGN CONSIGNEE AS FOLLOWS:

DR. HUBERT VARONIER

11, RUE EMILE-YUNG

1205 GENEVA, SWITZERLAND

LOT NO. S0110D 9 CC./72 VIALS.

KISSINGER

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NNN

Message Attributes

Automatic Decaptioning: X
Capture Date: 01 JAN 1994
Channel Indicators: n/a
Current Classification: UNCLASSIFIED
Concepts: CHEMICALS, GLASS CONTAINERS, RECALLS
Control Number: n/a
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Draft Date: 29 OCT 1975
Decaption Date: 01 JAN 1960
Decaption Note:
Disposition Action: n/a
Disposition Approved on Date:
Disposition Authority: n/a
Disposition Case Number: n/a
Disposition Comment:
Disposition Date: 01 JAN 1960
Disposition Event:
Disposition History: n/a
Disposition Reason:
Disposition Remarks:
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Drafter: DHEW/FDA:JRWEINROTH
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Margaret P. Grafeld
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